PHARMACODE

Package leaflet: Information for the patient

Demeclocycline Hydrochloride DAWA 300mg and 150mg Capsules

(demeclocycline hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Demeclocycline Hydrochloride Capsules are and what they are used for

Demeclocycline Hydrochloride Capsules contain the active substance demeclocycline hydrochloride. This is an antibiotic (kills bacteria) belonging to the tetracycline group of antibiotics. It is used to treat a wide range of infections caused by bacteria.
Some of these infections are:
- Severe acne
- Infections of the brain and liver caused by the bacteria Leptospira
- Infection caused by Brucella bacteria (brucellosis)
- Infections caused by Rickettsiae micro-organisms transmitted by lice, fleas, ticks and mites
- Infections of the sex organs and organs associated with urination (genito-urinary infections) such as an infection called chancroid, non-gonococcal urethritis
- Rare infections such as Tularaemia and bubonic plague.

It may also be used to treat a rare condition in which a tumour of the pituitary gland in your brain causes the amount of sodium in your blood to be too low.

2. What you need to know before you take Demeclocycline Hydrochloride Capsules

DO NOT take Demeclocycline Hydrochloride Capsules if:
- You know that you are allergic to any tetracycline antibiotic, including Demeclocycline, or to any of the other ingredients (see section 6 of this leaflet)
- You have a genetic disorder of your enzymes called acute porphyria. This may affect your nervous system and cause abdominal pain, vomiting and weakness
- You have severe problems with your kidneys
- If the patient is under 12 years of age.

Speak to your doctor if any of these apply to you before you start taking this product.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Demeclocycline Hydrochloride Capsules if you:
- Are sensitive to the sun, or have ever had any sun related skin reactions. You should avoid direct sunlight or using sunlamps while you are taking this medicine
- Are suffering from any disease which affects your liver or kidneys which is not severe
- Suffer from myasthenia gravis, a condition characterized by muscle weakness, difficulty chewing and swallowing and slurred speech
- Suffer from Systemic Lupus Erythematosus, known as SLE (which is an allergic condition which causes joint pain, skin rashes and fever).

Other medicines and Demeclocycline Hydrochloride Capsules:

Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines.
In particular, the effects of Demeclocycline Hydrochloride Capsules may be altered if you are already taking:
- Warfarin, coumarins and phenindione which are medicines used to thin your blood
- Retinoids (such as acitretin or isotretinoin), which are used for acne treatment
- Penicillin antibiotics (e.g. amoxicillin)
- Migraine treatments e.g. ergotamine and methysergide
- Sucralfate and tripotassium dicitrato bismuthate, which are medicines used to treat stomach or gut ulcers
- Oral typhoid vaccine
- Strontium ranelate which is used to treat bone diseases
- Diarrhoea medicines e.g. kaolin
- Antacid medicines which contain magnesium or aluminium
- Supplements or medicines which contain iron, calcium, zinc, magnesium or aluminium.

If you need to go to the hospital for an operation whilst you are taking this product, tell your doctor that you are taking Demeclocycline Hydrochloride Capsules.

Demeclocycline Hydrochloride Capsules with food and drink:

The capsules should be swallowed whole with a glass of water and on an empty stomach.
Demeclocycline Hydrochloride Capsules will be less effective if taken at the same time as food, milk, dairy products or supplements containing iron, calcium, zinc, magnesium or aluminium (see instructions in Section 3 “How to take Demeclocycline Hydrochloride Capsules”).

Pregnancy and breast feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Demeclocycline Hydrochloride Capsules should not be taken during pregnancy and breast-feeding.

Driving and using machines:

This medicine can cause headaches, dizziness and disturbances in vision and rarely, with hearing. If this happens to you, do not drive or operate machinery until these symptoms have gone away or until you have finished taking the capsules.

3. How to take Demeclocycline Hydrochloride Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The following information is to give you an idea of the usual doses given to treat particular illnesses. Different doses may be prescribed and if this applies to you, discuss it with your doctor.

You should complete the course of capsules as prescribed by your doctor.

For most infections: A total of 4 capsules every day are needed. These can be taken as 2 capsules in the morning and 2 in the evening, or as 1 capsule four times a day.

For pneumonia: 2 capsules are usually taken three times a day.

For the treatment of low sodium in the blood: The starting dose is between 6 and 8 capsules each day, divided equally over the day. After a while this dose is reduced to between 4 and 6 capsules each day.
- Never take more capsules than the doctor has told you to. It will not help you get better any faster and could be harmful to you
- The capsules should be swallowed whole with plenty of water. You should take them while you are sitting or standing. Do not take them when you are lying down
- These capsules are best taken on an empty stomach. To make sure of this you should not eat a meal for at least an hour before, or for two hours after you need to take a dose. If you take them closer to a mealtime, there will be food in your stomach and they will not work as well. You should avoid large milky drinks during this time as well, although a small amount in tea or coffee doesn't matter
- Some medicines and vitamin/mineral products can stop this medicine working properly if they are taken together. These include indigestion remedies (antacids) and vitamin/mineral products that contain iron, calcium, zinc, magnesium or aluminium in any form. If you need to take any of these while you are taking Demeclocycline Hydrochloride, you should take them at least an hour before or two hours after taking your Demeclocycline Hydrochloride dose.

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If you take more Demeclocycline Hydrochloride Capsules than you should:
If you accidentally take too many capsules, call your doctor straightaway, or go to the nearest hospital casualty department. Take any remaining capsules and this leaflet with you so that the medical staff know what you have taken.

If you forget to take Demeclocycline Hydrochloride Capsules:
Take a dose as soon as you remember, and then carry on as before. However you should not take any more capsules than usual on one day to catch up for those missed on the previous day. Do not take two doses at the same time. If you are not sure, ask your doctor or pharmacist for advice.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, Demeclocycline Hydrochloride Capsules can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

If you notice any of the following side effects, stop taking the medicine and talk to your doctor as soon as possible.

Not known (frequency cannot be estimated from the available data)
- wheezing or shortness of breath
- blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'
- unusual bruising
- severe watery diarrhoea, unusually dark urine or a large increase or sudden decrease in the amount of urine, or a change in the frequency with which you need to pass water. You may become very thirsty and need to go to the toilet a lot more often than usual
- difficulty in swallowing
- weak feeling in your muscles
- severe chest pains, or severe pain in the stomach
- blurred vision, or a very bad headache that will not go away
- liver, kidney problems and disturbances of blood cells (shown by blood tests) have been reported, (symptoms of which include yellowing of the skin and whites of the eyes, sore throat, mouth ulcers, difficulty in passing urine, back pain).

Most of the other side effects that may occur are mild and can include:
- an upset stomach, feeling sick or being sick
- heartburn
- dizziness, disturbed hearing
- thrush (vaginal itch and discharge caused by fungal infection)
- increased sensitivity to the sun/sunlamps (possibly causing sunburn).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the MHRA Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Demeclocycline Hydrochloride Capsules
- Keep this medicine out of the sight and reach of children.
- Store in original package in order to protect from light and moisture.
- Do not use after the expiry date. This date is printed on your pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information
What Demeclocycline Hydrochloride Capsules Contain:
The active substance contains either 150 mg or 300 mg of demeclocycline hydrochloride.

The other ingredients are: microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate and gelatin capsule shell.
Capsule shell contains iron oxide yellow (E172), iron oxide red (E172), titanium dioxide (E171), gelatin and purified water.

What Demeclocycline Hydrochloride Capsules looks like and contents of the pack:
Demeclocycline Hydrochloride 150 mg Capsules are light brown caps with dirty yellow body hard gelatin size '2' capsule filled with yellow granular powder.

Demeclocycline Hydrochloride 300 mg Capsules are maroon caps with dirty yellow body hard gelatin size '0' capsule filled with yellow granular powder.

Pack size:
Blister pack of 28 capsules

Manufacturer:
Drugsrus Limited
5 Sandridge Close,
Harrow, Middlesex,
HA1 1XD,
United Kingdom

Marketing Authorisation Holder:
DAWA Limited
5 Sandridge Close,
Harrow, Middlesex,
HA1 1XD,
United Kingdom

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